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June 13, 2022

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I write to urge the Food and Drug Administration (FDA) to expedite consideration of removal of the requirement for the three-month blood donation deferral period for men who have sex with men (MSM) and implement individual-based risk assessment measures. As of April 2022, Canadian health authorities announced their intention to remove their three-month blanket deferral period for MSM prospective donors and are relying on individual-based risk assessment measures throughout the blood donation process.¹ The United States should accelerate efforts toward the goal of ending this discriminatory policy, which does not impact the safety or quality of donated blood.

It is widely acknowledged in the scientific and medical communities agree that eligibility for blood donation should be based on individual risk and that determining eligibility solely on sexual orientation and gender identity is not a necessary safety measure when considering the risk of blood-based diseases such as HIV/AIDS. In addition to risk assessment measures, FDA-qualified blood donation centers are required to screen donated blood for blood-borne diseases. As part of implementing the recently lifted ban, Canada will institute a new donor screening approach. In addition to Canada, seven other nations recently lifting blood donation restrictions on gay and bisexual men including the United Kingdom, Greece, France, Israel, Hungary, Denmark, and Brazil.² It is clear that the three-month deferral requirement is not only unnecessary, but hurtful to willing donors turned away only for their sexual orientation and harmful for the millions of Americans in need of blood transfusions during this shortage.

In October of 2020, the FDA changed its abstinence requirement for MSM blood donors from twelve months prior to donation to three months in response to the Red Cross' declaration of a first-ever blood crisis due to the Covid-19 pandemic. Despite this reduction in the deferral period, the FDA's three-month deferral requirement threatens the ability of our nation's hospitals to maintain a plentiful and consistent blood supply, especially considering the current national blood shortage. The Centers for Disease Control (CDC) and the World Health Organization (WHO) do not list sexual contact with men as a risk factor for HIV/AIDS. This deferral period, as required by the FDA, is not an essential measure to prevent disease in blood donation practices, but a discriminatory and stigmatizing barrier to the LGBTQI+ community.

¹ "Health Canada authorizes Canadian Blood Services' submission to eliminate donor deferral period for men who have sex with men," Health Canada, April 28, 2022, <https://www.canada.ca/en/health-canada/news/2022/04/health-canada-authorizes-canadian-blood-services-submission-to-eliminate-donor-deferral-period-for-men-who-have-sex-with-men.html>

² "Canada Removes Blood Ban on Donations from Gay Men," BBC News, April 28, 2022, <https://www.bbc.com/news/world-us-canada-61265645>

June is Pride Month, a time for members of the LGBTQI+ community and allies to celebrate the history of the community and acknowledge their resilience against discrimination and stigma. Additionally, June 14, 2022 is World Blood Donor Day. It is my hope that you join in acknowledgement of Pride Month and World Blood Donor Day as you reconsider the FDA's blood donor deferral policies

I urge you to remove the three-month deferral period for blood donation and implement individual risk assessment measures to replace this discriminatory policy. Thank you for your time and consideration of this most important issue. I look forward to your response.

Sincerely,

A handwritten signature in blue ink that reads "Brian Higgins". The signature is stylized with a large "B" and a long horizontal stroke at the end.

BRIAN HIGGINS
Member of Congress